DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 2 1 1999

NDA 12-616/S-062

Searle
Attention: Ms. Ingrid M. Hoos
4901 Searle Parkway
Skokie, IL 60077

Dear Ms. Hoos:

Please refer to your supplemental new drug application dated January 25, 1999, received January 26, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aldactazide (spironolactone with hydrochlorothiazide) Tablets.

This supplemental new drug application provides for final printed labeling revised to include the following statement at the end of the **ADVERSE REACTIONS** section under spironolactone:

Renal: Renal dysfunction(including renal failure)

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling included in your January 25, 1999 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 2 1 CFR 3 14.80 and 314.81.

If you have any questions, please contact:

Mr. Gary Buehler
Regulatory Health Project Manager
(301) 594-5332

Sincerely yours,

Raymond J. M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research